REMARKS

Claims 1-14 are pending in the application. Claims 1-3 and 5-14 were rejected under 35 U.S.C. § 112, first paragraph. Claim 4 was objected to as depending from a rejected base claim. The rejection and objection are addressed as follows.

First, Applicants note that this Office Action was made final, on the basis that Applicants' amendments necessitated the present rejection under § 112, first paragraph. Applicants respectfully submit that this is not the case and, thus, request that the finality of the Office Action be withdrawn. In particular, Applicants submit that the subject matter upon which the rejection under § 112, first paragraph is based, relating to the use of mono-hydroxylated amino acids other than 4-hydroxyisoleucine and poly-hydroxylated amino acids in connection with inducing insulin-sensitizing or insulin-mimetic effects, was present in the claims as filed. Thus, if the Examiner had wanted to reject the claims due to this subject matter, then this rejection should have been made in the first Office Action. Other than claim 14, the claims were not examined on their merits in the first Office Action, on the basis that claims 1-13 were found to be drawn to non-statutory subject matter. However, such a finding does not support examination that lacks consideration of the other statutory requirements for patentability. This is made clear, for example, in M.P.E.P. § 2105, which discusses the approach to be used when examining a claim to non-statutory subject matter (in this example, naturally occurring, living subject matter):

> If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made.

There is no reason to believe that this standard does not apply to other types of non-statutory subject matter. Thus, it is clear that, regardless of whether a claim is drawn to statutory subject matter, examination with respect to other statutory requirements must take place. In the present application, therefore, Applicants' amendment did not necessitate the rejection under § 112, first paragraph, and the finality of this Office Action should therefore be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-3 and 5-14 were rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner states that although the application enables a method of inducing an insulin sensitizing or insulin mimetic effect in a tissue of a patient by administration of 4-hydroxyisoleucine and/or the lactonic form thereof, use of other mono- or poly-hydroxylated amino acids for this purpose is not enabled. In the interest of expediting prosecution, Applicants have amended claim 1 to specify the use of 4-hydroxyisoleucine (and/or the lactonic form thereof) in the claimed method, which the Examiner has deemed to be enabled. Applicants thus respectfully request that this rejection be withdrawn.

Claim Objection

Claim 4 was objected to for depending from a rejected base claim, and was indicated to be allowable if rewritten in independent form, including the limitations of the base claim. As is noted above, the limitations of claim 4 (4-hydroxyisoleucine and/or lactonic forms thereof) have been added to the claim from which it depends, claim 1. Applicants thus submit that is objection should be withdrawn.

Claim Amendments and New Claims

In addition to the amendment suggested by the Examiner to obtain allowance, Applicants have made minor amendments to the claims, as discussed below. Further, Applicants have added additional claims to the application. The minor amendments to the existing claims, as well as the newly added claims, relate to subject matter that the Examiner has deemed to be allowable. Thus, Applicants respectfully request entry of the amendments and the new claims. The amendments and new claims are discussed as follows.

As is noted above, the limitations of claim 4 have been added to claim 1, from which claim 4 originally depended. Claim 4 has thus been canceled.

Claims 2, 3, and 13 have been amended to specify 4-hydroxyisoleucine and/or the lactonic form thereof, to be consistent with amended claim 1, from which these claims depend.

Claim 6 has been amended to specify that the patient of claim 1 "has or is at risk of developing insulin resistance" (new text is underlined). Support for this amendment can be found, for example, at page 1, lines 5-9, and at page 3, lines 25-28 of the application as filed.

Claim 12 has been amended to specify that the patient treated according to the method of claim 1 has or is at risk of developing diabetes. Further, new independent claim 22 has been added to cover the treatment of diabetes by inducing an insulin sensitizing or insulin mimetic effect by 4-hydroxyisoleucine (and/or its lactonic form) administration. Support for this amendment to claim 12 and new claim 21 can be found, for example, at page 3, line 25 to page 4, line 33.

Claim 14 has been amended in a similar manner as claim 1, to specify that the claimed

pharmaceutical composition or kit includes 4-hydroxyisoleucine and/or the lactonic form thereof, in addition to insulin.

New claims 15 and 16 are drawn to methods of inducing insulin mimetic (claim 15) or insulin sensitizing (claim 16) effects in a tissue of a patient by administration of 4-hydroxyisoleucine and/or a lactonic form thereof to the patient. Support for this amendment can be found in claim 1 as filed, which specifies both of these effects (i.e., insulin mimetic and insulin sensitizing effects) in a single claim. Support for this amendment can also be found, for example, at page 1, lines 5-9 of the application as filed.

New claim 17 specifies that the method of claim 1 further includes a step of insulin administration. Support for this new claim can be found, for example, at page 4, line 33 to page 5, line 2; page 5, lines 11-19; and page 10, line 18-19 of the application as filed.

New claim 18 specifies that the compound of claim 1 is orally administered to the patient. Support for this new claim can be found at page 5, line 20-23 and page 10, lines 12-14.

Further, new claims 19 and 20 specify that the compound of claim 1 is administered two (claim 19) or three (claim 20) times per day. Support for these new claims can be found, for example, at page 10, lines 16-18 of the application.

Finally, new claims 21 and 22 specify that the 4-hydroxyisoleucine and/or lactonic form thereof of claim 1 is in the form of a capsule (claim 21) or a tablet (claim 22). Support for this amendment can be found, for example, at page 10, lines 12-14 of the application.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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